External Cephalic Version with uterine-relaxation: atosiban versus fenoterol; a multi centre trial.

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External cepahlic version (ECV) of the fetus in breech position is a safe and relative simple obstetric intervention to reduce the incidence of caeserean section for breech position at term. Uterine relaxants can enhance the success rate of ECV with...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20784

Bron
NTR

Verkorte titel
ECV with uterine relaxation

Aandoening

stuitligging, uitwendige versie, uterus relaxatie, atosiban, oxytocine antagonist, fenoterol, betamimetica.
UK: breech presentation, external cephalic version, uterine relaxation, atosiban, oxytocine antagonist, fenoterol, betamimetics.

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Succesfull version; number of cephalic presentations half an hour after the procedure;
2. Fetal presentation at delivery.

Toelichting onderzoek

Achtergrond van het onderzoek

External cephalic version (ECV) is proven effective to reduce the number of caesarean sections in breech presentation at term. Untill now, betamimetics are the only effective uterine relaxants; they increase the succes rate of ECV by 40% and consequently lower the number of caeserean sections. Nevertheless, this medication has side effects which often leads to palpitations. Therefore, implementation of this treatment is limited. In this study, we compare fenoterol with atosiban to find out if atosiban is comparable to fenoterol in women with a breech presentation at term.

Doel van het onderzoek

External cepahlic version (ECV) of the fetus in breech position is a safe and relative simple obstetric intervention to reduce the incidence of caeserean section for breech position at term. Uterine relaxants can enhance the success rate of ECV with 40%. Betamimetica (fenoterol) is proven effective as uterine relaxant in ECV, but has several side effects due to which it is not used on daily basis. This trial will compare the effectiveness of atosiban with fenoterol during ECV in women with a singleton fetus in breech presentation at term.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Comparison of a bolus atosiban 6,75 mg iv compared to a bolus 40 micrograms iv 15 minutes before ECV.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pregnant women (from 18 years of age) with a live singleton fetus in breech presentation;

2. 32 weeks of gestation and onwards.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contraindications to labour or vaginal birth;

2. Any contraindication to ECV;

3. Contra-indications for fenoterol or atosiban.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	806
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1767
NTR-old	NTR1877
Ander register	METC AMC : 26246
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A